DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
M2004n

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

November 19, 1998

Ref: 99-DAL-WL-3

WARNING LETTER

VIA FACSIMILE AND
FEDERAL EXPRESS

Ms. Evelyn V. Houghton
Authorized Official
Vice President Biologics Division
American Plasma, Inc.
719 Sawdust Rd., Suite 205
Spring, Texas 77380

Dear Ms. Houghton:

During an inspection of American Plasma, Inc., 1223 West 43rd Street, Houston, Texas, on October 22-30, 1998, our investigators documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

1. Failure to adequately determine the suitability of persons to serve as donors of source plasma [21 CFR 640.63 and 640.72]. A review of 46 plasma donor records revealed 12 donations with incomplete documentation on the medical history donor screening questions.

2. Failure to assure that employees have the necessary training to perform adequate donor processing and screening. [21 CFR 606.20].

3. Failure to maintain adequate written standard operating procedures for the training of personnel in new or updated forms/procedures. [21 CFR 606.160].

The investigator presented a list of observations (FDA-483) to Ms. Teresa Huggins, Regional Director, at the close of the inspection and a copy is being attached to this letter for your reference. The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct

these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

We acknowledge your response letter dated November 6, 1998, however, the previous inspection also disclosed similar donor screening deficiencies, which may be indicative of a more serious quality assurance problem. Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of any additional steps that you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the correction will be completed.

Please address your response to Gwen Gilbreath, Compliance Officer, at the above letterhead address. A copy of this letter is being sent to Mr. Russ Winther, President Biologics Division, SeraCare, Inc., Colorado Springs, Colorado.

Sincerely,

Sylvia G. Gett

for Joseph R. Baca
Dallas District Director

cc: Mr. Russ Winther, President
Biologics Division
SeraCare, Inc.
1225 Oakmoor Heights
Colorado Springs, Colorado 80906